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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,515	07/27/2001	Garry Taylor	21663/0193	7055

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Burton A. Amernick
Connolly Bove Lodge & Hutz LLP
P.O. Box 19088
Washington, DC 20036-0088

EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/915,515	Applicant(s) TAYLOR ET AL.	
	Examiner Michael Borin	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 7,8 and 15-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,9-14 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

1. Response to restriction requirement filed 10/27/03 is acknowledged. Applicant elected, without traverse, Group I, claims 1-14,21, drawn to method of identifying a neuraminidase inhibitor. Claims 15-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected group.

Further restriction

2. Upon further consideration of the elected group, it was determined that, because it was overlooked that claims 7,8 are drawn to a separate group, the following additional restriction requirement is deemed necessary.

Claims are examined on merits to the extent they read on elected species.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

IA. Claims 1-6, drawn to method of identifying a neuraminidase inhibitor, classified in class 702, subclass 27.

IB. Claims 7,8, drawn to, classified in class 424, subclass 94.3.

The inventions are distinct, each from each other because of the following reasons:

The enzyme conjugate of Group IB is patentably distinct from method of identifying a potential inhibitor, because they are not related as a product and method of making.

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Even if they were, the product of Group IB can be obtained by other methods, e.g., synthetically.

Because applicant indicated that the elected invention is method of identifying a neuraminidase inhibitor, invention IA is considered as constructively elected; claims 7,8 are withdrawn from consideration as drawn to non-elected Group.

3. Claims 1-6,9-14,21 are under consideration.

Information Disclosure Statement

4. Applicants' Information Disclosure Statement filed 11/19/2002 has been received and entered into the application. Accordingly, as reflected by the attached completed copies of forms PTO-1449, the cited references have been considered.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-6,9-14,21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject

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matter which applicant regards as the invention. The rejection is made for the following reasons:

- A. The specification provides no antecedent basis or description of SEQ ID No. 1 and structure coordinates as recited in claim 1, and therefore does not support the claims.
- B. The meaning of term "using" in claim 1a is not clear. There are no method steps associated with "using", and it is not clear how the structure is being used.

Further, it is not clear what is the difference between "applying" the structure (step 1b), and "using" the structure (as in step 1a), and how these steps are related (if any) to each other.

Claim Objections

6. In claim 1, step a: replace "a₁" with "a₂", and change "hemagglutinen" to "hemagglutinin"

7. Claim 13 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of the base claim. Applicant is

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required to cancel the claims, or amend the claims to place the claim in proper dependent form, or rewrite the claim in independent form.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-6,9-14,21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to method for identifying a potential inhibitor for a paramyxovirus Hemagglutinin-neuraminidase, comprising the step of using a three-dimensional structure of the paramyxovirus hemagglutinin-neuraminidase as defined by the structure coordinates comprising the amino acid residues 174, 175, 190, 192, 199, 234, 236, 237, 254, 256, 258, 262, 299, 302, 317, 363, 364, 369,401, 416, 466, 498 and 526 according to SEQ ID NO: 1, and further comprising

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the steps of applying the three-dimensional structure to design or select the potential inhibitor, and obtaining the potential inhibitor.

The specification does not describe either SEQ ID No. 1 or the particular residues indicated in the claim. There is no information whether said residues, which locations spans through more than 450 residues, represent an interaction site, or plurality of interaction sites, or any other particular three-dimensional structure(s). Consequently, it is not clear how to identify an inhibitor to a non-identified interaction site(s). Specification addresses use of paramyxovirus hemagglutinin-neuraminidase atomic coordinates for computational design of an inhibitor as an objective of the invention in general, but fails to provide guidance on how to apply said coordinates. It is noticed that Figure 3 displays some of the residues addressed in the claim; however, again, it is not known whether the residues recited in the claims represent one or more different interaction sites.

Therefore, insufficient guidance exist in the specification to enable a person of skill in the art to practice the invention without the need for undue experimentation.

9. Further, even if claims 1-6,9-13,21 have been enabled for method for identifying a potential inhibitor for a Newcastle disease virus (NDV) paramyxovirus Hemagglutinin-neuraminidase, the claims would not been enabled for design of

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inhibitors for method for identifying a potential inhibitor for any other paramyxovirus Hemagglutinin-neuraminidase, because the residues recited in claim 1 are limited to SEQ ID No. 1 which is the sequence of hemagglutinin-neuraminidase from Newcastle disease virus. There are residues or coordinates specified for hemagglutinin-neuraminidase from any other sources. Note that within paramyxoviridae family hemagglutinin-neuraminidase sequenced vary widely in the range of 25% to 75% between species (see specification, p. 10, lines 2,3).

10. Furthermore, claims 1-6,9-14,21 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make the invention. The claims address steps of using and applying three-dimensional structure of paramyxovirus Hemagglutinin-neuraminidase; however the specification does not appear to disclose suitable algorithms or implementations for the said method steps.

Prior art made of record

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: WO 99/02965.

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Conclusion.

12. No claims are allowed

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

January 5, 2004

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

mlb

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.